forming each of a plurality of different selected reagent mixtures in the combined reagent-mixture stream by adjusting the flow rate of at least one of a plurality of reagent-mixture components in accordance with a respective flow-rate ratio of reagent-mixture components forming each selected reagent mixture; and

E2

analyzing the components of each selected reagent mixture.

Remarks

The Office action addressed claims 1, 3-6, 31 and 33-44 each of which were rejected under 35 U.S.C. §102(b).

Claims 1, 5, and 31 have been hereby amended to more particularly point out and distinctly claim Applicants' invention and claims 1, 3-6, 31 and 33-44 remain pending in the present application. In view of the above amendments and the following remarks, it is respectfully submitted that these claims are allowable.

Claims 1, 3-6, 31 and 33-44 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent Nos. 4,420,564 to Tsuji et al (below referred to as "Tsuji"), 5,192,509 to Surjaatmadja et al (below referred to as "Surjaatmadja"), 4,804,519 to Sainz et al (below referred to as "Sainz") and 5,260,027 to Kuroda (below referred to as "Kuroda"). However, Applicants respectfully traverse this rejection as none of these references, either taken alone or in any combination thereof, teach or suggest an apparatus or method for analyzing a plurality of reagent-mixtures wherein one of the reagent mixture components includes a sample of blood and wherein the flow rate of at least one of the reagent mixture components may be varied for forming a plurality of different selected reagent mixtures as now defined in Applicants' independent claims 1 and 31. Also, none of these references, either taken alone or in any combination thereof, teach or suggest a first inlet port located at an upstream end of a mixing chamber and a second inlet port located downstream of the first inlet port wherein one of the first and

second inlet axes is inclined at an acute angle relative to the other as defined in Applicants' independent claim 42.

Tsuji

As illustrated in FIG. 5, Tsjui teaches a blood sugar analyzer for measuring the concentration of blood sugar in a specimen. The blood sugar analyzer includes a sugar measurement sensor 1 and a temperature electrode 2 disposed in a reaction cell CE. A buffer liquid 4 is delivered by liquid pump 3 to the cell CE for washing the interior of the cell CE. An air pump 6 is provided for vibrating a silicon diaphragm SD for stirring a blood specimen to be tested. A temperature sensor 7 detects the temperature of the cell CE and a heater 8 functions to heat the cell block SB to a particular temperature. A control device CC composed of a minicomputer CPU measures and controls the temperature of the cell block SB and controls operation of the liquid pump 3 and air pump 6. The CPU also receives input from the blood sugar sensor 1 via a differential amplifier 21, an A/D converter 22 and buffer 23. See col. 4, lines 1-61.

It is important to note that Tsuji makes no mention of varying the flow rate of either the blood sample or the standard solution in order to provide various mixtures thereof. In particular, column 7, line 40 states that a blood sample may be "introduced" but does not describe how this is accomplished. Column 7, lines 51-53 state that a standard solution may also be "introduced" and that the "...standard solution setting switch DS2 on the control panel AN of FIG. 3 is adjusted so as to indicate the concentration in the standard solution." In this way, the operator inputs what the concentration of the standard solution to be "introduced" is to the control panel for use by the device in calibration and in calculating blood sugar level of the blood sample. Thus, neither flow rates or even mixtures of the blood sample or standard solution is contemplated by Tsuji.

Moreover, Tsuji is concerned with providing a device, as discussed in col. 11, lines 25-40, for measuring blood sugar levels at appropriate temperatures. In particular, the CPU detects the temperature of the cell CE and energizes the heater 8 if necessary. When the temperature is in a target temperature range, the CPU automatically determines the effects of the particular temperature on the measurement of blood sugar concentration and compensates therefor.

Discussion

Applicants respectfully submit that Tsuji fails to anticipate or render obvious either of Applicants independent claims 1 or 31 as this reference fails to teach or suggest an apparatus or method for analyzing a plurality of reagent-mixtures wherein the flow rate of at least one reagent mixture component may be varied for forming a plurality of different selected reagent mixtures as now defined in Applicants' independent claims 1 and 31. Instead, as discussed above, Tsuji teaches a blood sugar analyzer which is directed to compensating for temperature variations during blood sugar measurements. Tsuji is wholly devoid of any discussion concerning varying flow rates of either blood samples or other solutions mixed therewith in order to vary the concentration thereof. Accordingly, Tsuji fails to anticipate or render obvious Applicants' independent claims 1 and 31.

In addition, Applicants respectfully submit that each of dependent claims 3-6 and 33-41 are patentable over Tsuji for the same reasons discussed above in view of their dependency on claims 1 and 31. Further, Applicants submit that each of claims 3-6 and 33-41 define separately patentable subject matter. For example, claim 3 defines that the means for forming a plurality of different selected reagent mixtures is coupled to and controls the flow rate of each pump. No such comparable means is taught or suggested by Tsuji. Also, claim 5 defines a control unit comprising a database of predetermined

reagent-mixture ratios wherein each predetermined reagent-mixture ratio corresponds to one or more animal species. No such control unit is taught or suggested by Tsuji.

Concerning claims 42-44, independent claim 42 defines a first inlet port located at the upstream end of a mixing chamber and a second inlet port located downstream of the first inlet port and wherein one of the first and second inlet axes is inclined at an acute angle relative to the other. No such arrangement is taught or suggested by Tsuji. In particular, Tsuji is completely silent with respect to any mixing chamber and thus does not anticipate nor render obvious Applicants' claims 42-44.

Surjaatmadja

Surjaatmadja discloses an apparatus for automatic titration that, as illustrated in the Figure, has a sample solution source 12 and a plurality of reservoirs of titrants 18, 20, 26 each connected to a respective plurality of pumps 30, 32, 34, 36. A central computer 40 controls individual pump speeds and therefore the pump output mix through a delivery tube 44 that delivers fluid mixture through an ultrasonic mixer 46 to a tube 56. A color detector 60 is disposed adjacent to tube 56 and functions to detect indicator color changes of the liquid for providing indication thereof to the central computer 40. See Abstract lines 1-13.

It is important to note that Surjaatmadja is wholly concerned with the titration of elements through the sampling of well bore fluid (see col. 4, lines 1-24 with particular regard to lines 1-2) and does not provide any database for establishing a particular flow rate for the pumps.

Discussion

Applicants respectfully submit that Surjaatmadja also fails to anticipate or render obvious Applicants' independent claims 1 and 31 as this reference fails to teach or suggest analyzing a plurality of reagent-mixtures wherein one of the reagent mixture

components includes a sample of blood and the flow rate of at least one of the reagent mixture components may be varied as defined in Applicants' independent claims 1 and 31. In contrast, as discussed above, Surjaatmadja is concerned with identifying particular elements through titration of well bore fluid through a color detector and does not discuss analyzing blood or blood samples. Much less discuss chemically analyzing or analyzing particle distribution of a reagent mixture component including a sample of blood. Accordingly, Surjaatmadja does not anticipate or render obvious Applicants' independent claims 1 and 31.

In addition, Applicants respectfully submit that each of dependent claims 3-6 and 33-41 are patentable over Surjaatmadja for the same reasons discussed above in view of their dependency on claims 1 and 31. Further, Applicants submit that each of claims 3-6 and 33-41 define separately patentable subject matter. For example, claim 5 defines a control unit comprising a database of predetermined reagent-mixture ratios wherein each predetermined reagent-mixture ratio corresponds to one or more animal species. No such control unit is taught or suggested by Surjaatmadja.

Concerning claims 42-44, no such mixing chamber arrangement as defined therein and discussed above is taught or suggested by Surjaatmadja and thus, this reference does not anticipate nor render obvious Applicants' claims 42-44.

Sainz

As illustrated in Figure 2, Sainz discloses a sample analysis apparatus for material spectrometry including a sample tube 12 connected to a mixing device 24 via an inlet 22. A diluent (kerosene) reservoir 34 is provided which is connected to the mixing device 24 via line 28 and pump section 30. A tubing line 36 is connected to an outlet 38 of the mixing device 24, through a pump section 40 and to a debubbler unit 46 mounted adjacent a torch 52. As described in col. 3, lines 11-20, pumps 30 and 40 are operated by

a drive motor 94 with pump 40 pumping at a higher rate than pump 30 by use of pump tubes of differing internal diameters.

Discussion

Applicants respectfully submit that Sainz fails to anticipate or render obvious Applicants' independent claims 1 and 31 as this reference also fails to teach or suggest analyzing a plurality of reagent-mixtures wherein one of the reagent mixture components includes a sample of blood and the flow rate of at least one of the reagent mixture components may be varied as defined in Applicants' independent claims 1 and 31. In contrast, as discussed above, Sainz is concerned with material spectrometry via a torch 52 and use of the diluent kerosene and does not discuss analyzing blood or blood samples. Accordingly, Sainz also does not anticipate or render obvious Applicants' independent claims 1 and 31.

In addition, Applicants respectfully submit that each of dependent claims 3-6 and 33-41 are patentable over Sainz for the same reasons discussed above in view of their dependency on claims 1 and 31. Further, Applicants submit that each of claims 3-6 and 33-41 define separately patentable subject matter. For example, claim 3 defines that the means for forming a plurality of different selected reagent mixtures is coupled to and controls the flow rate of each pump. No such comparable means is taught or suggested by Sainz. Also, claim 5 defines a control unit comprising a database of predetermined reagent-mixture ratios wherein each predetermined reagent-mixture ratio corresponds to one or more animal species. No such control unit is taught or suggested by Sainz.

Concerning claims 42-44, independent claim 42 defines a first inlet port located at the upstream end of a mixing chamber and a second inlet port located downstream of the first inlet port and wherein one of the first and second inlet axes is inclined at an acute angle relative to the other. No such arrangement is taught or suggested by Sainz. In particular, Sainz discloses a mixing chamber as illustrated in FIG. 3 having inlet ports

122 and 124 which are located in a mixing cavity 102 such that they are not upstream or down stream as defined in Applicants' claim 42. Instead, they are located in about the same point of the flow stream. See col. 3, lines 21-35. Accordingly, Sainz does not anticipate nor render obvious Applicants' claims 42-44.

Kuroda

Kuroda teaches a method and apparatus for automatically analyzing particles using plural analyzing modules. As illustrated in FIGS. 2 and 3, the apparatus includes a quantitative picking means 16 having liquid dispensing means S1 and S2, suction pump S3, sample suction valve 28, measuring unit 18, analyzing module 12 and analyzing device 14 connected thereto. The quantitative picking means 16 comprises a sampling valve 17 composed of a movable element 26 separated by stationary elements 22 and 26.

It is important to note that a specimen sample is merely premeasured and placed into sample container 20 and is simply forced by low pressure into the valve 17 during operation. See col. 8, lines 27-31. Samples of other solutions such as a diluent are premeasured and located in the liquid dispensing means S1 and S2 which are simply dispensed into the valve 17. See col. 8, lines 33-41. Kuroda simply fails to discuss varying any flow rate or varying any sample mixtures.

Discussion

Applicants respectfully submit that Kuroda fails to anticipate or render obvious either of Applicants independent claims 1 or 31 as this reference fails to teach or suggest an apparatus or method for analyzing a plurality of reagent-mixtures wherein the flow rate of at least one reagent mixture component may be varied for forming a plurality of different selected reagent mixtures as now defined in Applicants' independent claims 1 and 31. Instead, as discussed above, Kuroda teaches an analyzer having a valve which separates a specimen into slices for quantifying a sample. See col. 8, lines 3-24. Indeed,

Kuroda is wholly devoid of any discussion concerning varying flow rates of either blood samples or other solutions mixed therewith in order to vary the mixture thereof. Accordingly, Kuroda fails to anticipate or render obvious Applicants' independent claims 1 and 31.

In addition, Applicants respectfully submit that each of dependent claims 3-6 and 33-41 are patentable over Kuroda for the same reasons discussed above in view of their dependency on claims 1 and 31. Further, Applicants submit that each of claims 3-6 and 33-41 define separately patentable subject matter. For example, claim 3 defines that the means for forming a plurality of different selected reagent mixtures is coupled to and controls the flow rate of each pump. No such comparable means is taught or suggested by Kuroda. Also, claim 5 defines a control unit comprising a database of predetermined reagent-mixture ratios wherein each predetermined reagent-mixture ratio corresponds to one or more animal species. No such control unit is taught or suggested by Kuroda.

Concerning claims 42-44, independent claim 42 defines a first inlet port located at the upstream end of a mixing chamber and a second inlet port located downstream of the first inlet port and wherein one of the first and second inlet axes is inclined at an acute angle relative to the other. No such arrangement is taught or suggested by Kuroda. In particular, Kuroda fails to discuss how fluids are mixed and thus does not anticipate nor render obvious Applicants' claims 42-44.

As stated in the preliminary amendment dated February 7, 2000 and repeated hereafter, the feature as defined in claims 1 and 31 provides significant advantages over the prior art. One advantage is that the mixture ratio of the reagent mixture may be adjusted at any time, either before or during analysis, by adjusting the flow-rate ratio of the reagent-mixture components. *See* page 18, lines 10 through 23 of the present specification. As also described in the present specification, if, for example, a blood-cell abnormality is detected during hematological analysis, the blood-dilution ratio (which defines the reagent mixture) may be adjusted to further assess the abnormality. With the

prior art apparatus, on the other hand, in which the sample batches are prepared in mixing cuvettes, this would require additional samples to be taken or used to further assess the abnormalities. *Id.* Another advantage of creating the reagent mixtures in this manner (as opposed, for example, to using a mixing cuvette), is that a lesser volume of the reagent-mixture components (e.g., blood samples) may be employed. *See* pages 17-18, lines 24 through 9 of the present specification. Yet another advantage of this claimed feature is that in the veterinary market, for example, the system may automatically make the different reagent mixtures for a variety of different animal species by adjusting the flow-rate ratios in accordance with, for example, a database of information pertaining to the reagent-mixture ratios for the different species. *See* page 14, lines 13 through 21.

Neither these advantages, nor the solution of the present invention for achieving these advantages, as specifically defined in amended independent claims 1 and 31, are taught or suggested by the cited prior art.

Copies of Cited References

The Examiner states in the Office action that the parent application is unavailable and requests selected copies of the art cited in Applicants' Information Disclosure Statement dated August 9, 1999, however, copies of these documents are not readily available at this time to the Applicants. Accordingly, the Examiner is requested, in accordance with MPEP § 609 to consider these references without additional copies being supplied. MPEP § 609 states that when a related application is filed additional copies of references are not required to be submitted (see page 600-100).

Conclusion

In view of the foregoing, reconsideration, re-examination and allowance of each of the presently pending claims 1, 3-6, 31, and 33-44 is respectfully requested. All issues raised by the Examiner having been addressed, an early allowance of all pending claims is earnestly solicited.

A Petition for One Month Extension for response to the Office action accompanies this response along with a check for $55.00. No other fee in addition to that submitted herewith is believed to be required. However, if any additional fees are required, or otherwise if necessary to cover any deficiency in fees already paid, authorization is hereby given to charge our Deposit Account No. 11-0231.

Respectfully submitted,

By _____

Roger C. Phillips (Reg. No. 37,418)
Mark D. Giarratana (Reg. No. 32,615)
Attorneys for Applicant

PTO Correspondence Address:

Cummings & Lockwood
Granite Square
700 State Street
P.O. Box 1960
New Haven, CT 06509-1960
Phone: (860) 275-6719
Fax: (860) 560-5919